



For Immediate Release

Contact: Craig Orfield
(202) 224-6770

Wednesday, July 25, 2007

Statement of Michael B. Enzi

Senate Committee on Health, Education, Labor and Pensions

Markup of S. 625, the Family Smoking Prevention and Tobacco Control Act

July 25, 2007

Mr. Chairman, The bill we are marking up today is ambitiously called the Family Smoking Prevention and Tobacco Control Act. Well, I've carefully studied this bill. I've read all 168 pages. I can tell you that it will neither prevent families from smoking nor effectively control tobacco. That's what this fatally flawed bill won't do. What will it do? It will undermine the Food and Drug Administration's mission of making our nation's food and drug supply safe. Right now our efforts should be focused on renewing important expiring authorities and reforming our drug safety system, not on giving the agency new authorities that conflict with its basic mission. We should also be looking at ways to make our food safety surveillance system stronger instead of fooling people into believing that tobacco products can ever be safe.

But here we are. This bill is fatally flawed. It is a dinosaur that has not significantly changed in years. It represents billions of dollars wasted, but very few tobacco users helped. The extensive bureaucracy created by this bill won't make Americans safer. The Congressional Budget Office scored this bill in 2004. They found that the bill would lead to essentially no reduction in adult smoking, and only a 12.5% reduction in youth smoking. There are currently 2.7 million youth smokers, 87.5% of whom will keep smoking under this bill. That's what you get for \$450 million a year in user fees. I know we can do better.

Most people want to do something about the scourge of tobacco. This bill has been out there for several years, and a lot of mythology has grown up around it. So, I'd like to take a couple of minutes to walk through what the bill does. And more importantly, what it does NOT do.

The bill duplicates many existing functions that are currently executed by the Tax and Trade Bureau of the Department of Treasury. I don't mean the bill moves those functions to FDA; I mean the bill duplicates them. So companies register twice. They report the same data twice. They fill out the same forms twice. The least this bill could have done is struck those functions from Treasury. But the desire for FDA regulation of tobacco seems to have trumped common sense.

Let's focus for a moment on what FDA regulation of tobacco really means. We all know there is no such thing as a safe cigarette. A cigarette reviewed by FDA for marketing would send a terrible public health message and would undermine the agency's credibility. The bill takes the wrong approach – forcing FDA to regulate tobacco, but preventing them from banning it. This ties the agency's hands and puts them in conflict with their own mission on safety.

FDA review and approval of tobacco products sends a terrible public health message - creating the sense that cigarettes are safe or can be made safer, when we know they cannot. Some will tell you that I am wrong about this, and the bill has been changed so that FDA is not approving tobacco products. Well, I have gone over the clever wordsmithing, and I think the new language is a distinction without a difference. The bill still would require tobacco companies to submit an application to FDA to market a new product. However, instead of using the word "approval," the bill now states that FDA issues an "order" permitting the product to be marketed. Issuing an order permitting marketing is basically the same thing as approval. A crafty word game doesn't cure a fatally flawed bill—and it doesn't stop people from using tobacco.

Of course, no matter what you call the process of getting to market, public perception is the key here. And under this bill, the public will think FDA is approving tobacco products, and that those products are somehow safer. The bill also contains a new provision that says companies can't put a label on the package saying the product has been approved or cleared by FDA. People will tell you "well, that should shut Enzi up," but they haven't been listening to what I've been saying. The product would still be cleared or approved by FDA. That is the essence of the problem. FDA approves cures, not poisons.

The FDA cannot be put in the position of approving a product which years of science and the deaths of far too many Americans has shown to be dangerous. Simply put, tobacco kills people. We can do better. We should focus our efforts instead on helping people quit using tobacco, or better yet, to never start.

The bill requires FDA to promulgate product standards for tobacco products. This is tinkering at the margins, trying to make a deadly product slightly less deadly, instead of trying to get rid of it. The only way to make tobacco products safer is not to ever use them in the first place.

We should be spending our time conferencing the expiring drug and device user fee programs and drug safety reform. Instead we are here, pursuing the folly of trying to

snatch safety from the jaws of a dangerous beast. The user fee program contemplated by this bill would be even larger than the drug user fee program. Think about that for a minute. The reauthorization of the drug user fee program we are supposed to be working on would support 1,925 full-time equivalents, or staff for next year. And this program would be bigger. Where are these TWO THOUSAND professional staff going to come from? FDA is shorthanded as it is. You can't pull people out of existing jobs, or those critical mission areas at FDA will go unfulfilled. I don't think there are any answers to this, but I think the question is worth asking.

I think you have all heard plenty about how this bill is a compromise with the biggest of Big Tobacco, so I won't go back over that ground, other than to say that I think legislating is about compromise, but you can't compromise your principles. We can do better. We must win the war on tobacco, not sign a peace treaty with Phillip Morris.

You might wonder why I have waited until now to propose a solution to the war on tobacco. Quite frankly, I didn't ever think that this bill, S. 625, would be seriously considered by this Committee—since it only pays lip service to eliminating deadly tobacco products from the market.

I have developed my own tobacco legislation that would truly have an impact on the number of smokers in this country. My bill, the Help End Addiction to Lethal Tobacco Habits, or the HEALTH Act, was introduced last week. I decided not to offer it as an amendment today because I don't want to direct precious time and resources from the task of promptly completing the conference on drug safety reform and other important FDA bills that are expiring soon. After that process is completed, I will focus my efforts on passing a tobacco prevention bill that truly prevents smoking and controls tobacco.

My bill contains a novel cap-and-trade program - guaranteeing that fewer people suffer the deadly consequences of smoking, while providing flexibility in how those reductions are achieved.

Cap-and-trade programs have a proven track record in the environmental arena. In the 1980s, lakes and forests were dying from acid rain. The acid rain was caused by emissions of sulfur and nitrogen oxides from power generation at electrical plants. The Clean Air Act Amendments of 1990 instituted a system of allowances for emissions of sulfur and nitrogen oxides that could be used, banked, traded or sold freely on the open market. The number of allowances decreased each year. This system achieved the desired results faster and at lower cost than had been anticipated. The cap-and-trade program for sulfur and nitrogen oxides has made dramatic differences in our air quality over the past 15 years, and is a resounding success. I propose to carry this market-oriented system over to the tobacco control arena. Although this has never been tried for a health issue, I think it will work.

My legislation will shrink the size of the tobacco market over the next 20 years. Smoking reductions are guaranteed, and companies are given time and flexibility to make the reductions or divest. In addition, small tobacco companies would have a valuable

asset in their allocations, leveling the playing field a bit between the smaller and larger industry members. Finally, and I think very importantly, public health groups could buy and retire allowances to achieve the reductions in tobacco use even faster than specified in my bill. I would like to issue a challenge today to those groups – use your clout to help me make this work. Stand with me to fight tobacco and protect the health of all Americans.

I will have a series of amendments to offer today, ones that I hope you will take seriously. I offer them to highlight where I think you have fallen short, and to show my commitment to doing what needs to be done to eliminate the scourge of tobacco in our lifetime. I hope you will join me in that commitment.